

## **REMARKS**

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-14, 16-18 and 20 are pending in this application. Claims 1-4, 6-10, 12-14, 16-18 and 20 are amended. Support for the claim amendments can be found throughout the specification. Particular support for the amendments to claim 16 can be found on page 47, line 27, on page 50, lines 6-8, and in cancelled claims 21 and 22. No new matter is added.

It is submitted that the claims are patentably distinct over the prior art and that these claim are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the amendments should not give rise to any estoppel, as they are not narrowing amendments.

#### **Oath/Declaration**

The Examiner is thanked for clarifying the requirement for a mailing address. An Application Data Sheet is enclosed herewith, supplying the necessary information.

#### **Specification**

An amended Abstract is enclosed, overcoming the objection to the use of acronyms.

### **II. THE REJECTIONS UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, ARE OVERCOME**

Claims 1-15 were rejected under Section 112, first paragraph, as allegedly lacking enablement. It is believed that the claim amendments sufficiently define the scope of the claims such that they are enabled. It is emphasized that the invention is not an NOI *per se*; rather, the invention is the treatment of pain through lentiviral-mediated delivery of the NOI to a dorsal root ganglion cell.

Claim 19 was rejected under Section 112, first paragraph, as allegedly lacking enablement. Claim 19 has been cancelled, rendering this rejection moot.

Claims 16-18 and 24 were rejected under Section 112, first paragraph, as allegedly lacking enablement. The claims have been amended to clarify that an identification or validation

method is performed *in vivo*, after an initial screening step *in vitro*. (See page 50, lines 12-13.) Examples of *in vitro* testing are known in the art, and are provided in the section beginning on page 47, line 7, of the specification. For example, the excitability of cells can be measured *in vitro* (page 49, lines 30-33), as can changes in transmission (page 50, lines 6-8). It is believed that claim 16 and dependent claims are enabled.

Claim 4 was rejected under Section 112, first paragraph, as allegedly lacking adequate written description. Claim 4 has been amended such that this rejection is obviated.

Reconsideration and withdrawal of the Section 112, first paragraph, rejections, are requested.

### **III. THE REJECTION UNDER 35 U.S.C. § 112, 2<sup>ND</sup> PARAGRAPH, IS OVERCOME**

Claim 18 was rejected under Section 112, second paragraph, as allegedly being indefinite. The phrase “derived from” has been removed from claim 18, overcoming the rejection. Reconsideration and withdrawal are requested.

### **IV. THE REJECTIONS UNDER 35 U.S.C. § 102 ARE OVERCOME**

Claims 16 and 20-24 were rejected under Section 102(a) as allegedly being anticipated by Goss *et al.* Claim 16 was rejected under Section 102(b) as allegedly being anticipated by Cuny *et al.* Neither Goss nor Cuny teaches a validation/identification method that includes an *in vitro* identification step, followed by an *in vivo* verification step. Therefore, the claims are not anticipated.

Reconsideration and withdrawal of the rejections under Section 102 are requested.

### **V. THE REJECTION UNDER 35 U.S.C. § 103 IS OVERCOME**

Claim 17 was rejected under Section 103(a) as allegedly being unpatentable over Cuny *et al.* in view of MacLeod *et al.* As discussed above, the prior art does not teach a two-step process having both an *in vitro* component and an *in vivo* component.

Reconsideration and withdrawal of the rejections under Section 103 are requested.

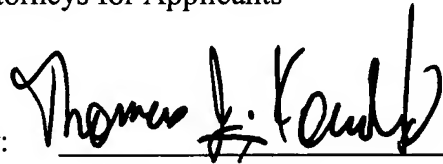
**CONCLUSION**

Applicants believe that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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By:

A handwritten signature in black ink, appearing to read "Thomas J. Kowalski", written over a horizontal line.

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